(2)

Supreme Court, U.S.
FILED
JUL 23 2001
OFFICE OF THE CLERK

No. 00-1766

In the Supreme Court of the United States

ELIZABETH KEMP AND CLIFFORD KEMP,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

THOMAS M. PARKER
Roetzel & Andress
222 South Main Street
Akron, Ohio 44308
(330) 376-2700

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Respondent

30 pp

QUESTION PRESENTED

The petition presents the question whether petitioners' state-law damages claims were preempted by 21 U.S.C. § 360k(a) on the ground that the Food and Drug Administration's grant of pre-market approval to Medtronic's 4004M pacemaker lead imposed specific federal requirements on that medical device. However, as we explain in this brief, that question is not in fact presented by this case.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

TABLE OF CONTENTS

Page

QUESTION PRESENTED I

RULE 29.6 STATEMENT ii

TABLE OF AUTHORITIES v

STATEMENT 1

A. The Regulatory Structure Of The Medical Device Amendments. 2

B. The Extensive Regulatory History Of The Model 4004M Device. 4

C. Petitioners' Case In The Lower Courts. 9

REASONS FOR DENYING THE PETITION 14

I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR*. 15

A. Petitioners Have Preserved No Claims That Would Be Affected By This Court's Intervention. 15

B. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption of State-Law Tort Actions Before Revisiting The Issue Itself. 17

C. While There Is Some Inconsistency In The Lower Courts, It Is More Limited Than Petitioners Assert. 18

TABLE OF CONTENTS – continued

Page

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE-LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT 23

CONCLUSION 28

TABLE OF AUTHORITIES

Page(s)

CASES

Black v. *Cutter Labs.*,
351 U.S. 292 (1956) 16

Brooks v. *Howmedica, Inc.*, 236 F.3d 966
(8th Cir.), *reh'g en banc granted*,
246 F.3d 1149 (8th Cir. 2001) 18, 20, 22

Buckman Co. v. *Plaintiffs' Legal Comm.*,
121 S. Ct. 1012 (2001) ..... *passim*

California v. *Rooney*, 483 U.S. 307 (1987) 16

Connelly v. *Iolab Corp.*, 927 S.W.2d 848
(Mo. 1996) 21

Fry v. *Allergan Med. Optics*, 695 A.2d 511
(R.I. 1997) 20, 22

Goodlin v. *Medtronic, Inc.*, 167 F.3d 1367
(11th Cir. 1999) 20

Green v. *Dolsky*, 685 A.2d 110 (Pa. 1996) 20, 22

Johnson v. *De Grandy*, 512 U.S. 997 (1994) 16

Martin v. *Medtronic, Inc.*, __ F.3d __,
2001 WL 682097 (5th Cir. 2001) 17, 20, 22

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*

Mitchell v. *Collagen Corp.*, 126 F.3d 902
(7th Cir. 1997) 20, 22, 25

The Monrosa v. *Carbon Black Export, Inc.*,
359 U.S. 180 (1959) 15

Niehoff v. *Surgidev Corp.*, 950 S.W.2d 816
(Ky. 1997) 21, 23

TABLE OF AUTHORITIES – continued

Page(s)

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) 22, 23

Papike v. *Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997) 22

Weiland v. *Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) 20, 21

Worthy v. *Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) 20, 22

STATUTES, RULES AND REGULATIONS

Food Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* 1

Medical Device Amendments, 21 U.S.C. § 360c *et seq.* ..... *passim*

21 U.S.C. § 331 24

21 U.S.C. § 351 24

21 U.S.C. § 360 24

21 U.S.C. § 360c ..... *passim*

21 U.S.C. § 360e ..... *passim*

21 U.S.C. § 360j 24

21 U.S.C. § 360k ..... *passim*

21 U.S.C. § 382 24

21 C.F.R. § 808.1 23

21 C.F.R. § 814.20 5

21 C.F.R. § 814.39 24

21 C.F.R. § 814.80 24

TABLE OF AUTHORITIES – continued

Page(s)

21 C.F.R. Pt. 820 7

21 C.F.R. § 820.01 8

S. Ct. R. 10 ..... 20, 22

MISCELLANEOUS

FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce, 97th Cong., 2d Sess. 5 (1982) 26

Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321 (Oct. 10, 1980) 20, 21

H.R. REP. No. 94-853 (1976) 2, 25, 26, 27

Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977) 19

United States Brief in *Buckman* Co. v. *Plaintiffs' Legal Comm.*, 121 S. Ct. 1012 (2001) 27

United States Brief in *Smith Indus. Med. Sys., Inc.* v. *Kernats*, No. 96-1405, 118 S. Ct. 684 (1998) (Mem.) 27

BRIEF FOR THE RESPONDENT IN OPPOSITION

Petitioners assert that the Court should grant review here because *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has caused confusion in the lower courts. However, this case, which was litigated below on grounds not presented in the petition, and which was decided by the Sixth Circuit consistently with both *Lohr* and the holdings of the great majority of lower courts, is not the vehicle in which to attempt to clarify the scope of preemption under Section 360k of the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

While the lower courts may be "sharply divided" in their interpretations of *Lohr* (Pet. 1, quoting Pet. App. 8a), the specific "sharp[] divide[s]" that the court of appeals referred to are not in fact presented in the petition; the first was decided below in part on state-law grounds, see Pet. 8 n.2; Pet. App. 84a, and the second was recently resolved by this Court in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001). The issues concocted for purposes of Supreme Court review do somewhat divide the lower courts, but those issues raise only academic questions in the context of this particular case.

STATEMENT

Tellingly, the petition provides almost no information about either the claims that petitioners actually raised below or about the pre-market approval ("PMA") process to which the specific medical device at issue was subjected. After briefly outlining the background legal structure applicable to preemption under the MDA, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA — in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state-law tort actions challenging the design, manufacture, or labeling of "Class III" devices (those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "pre-market notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-493.

The *Lohr* Court explicitly differentiated 510(k) approval of a device, which all members of the Court found not to pre-

empt at least certain state-law tort claims, from the PMA process for new devices, at issue in this case:

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review, *id.* at 479, and never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one needed to engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that were arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common-law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process — which focuses on "entirely generic concerns about device regulation generally" (*id.* at 501), that is, on the competitive disadvantage that would be caused if new items the substantial equivalent of a pre-

existing item were not easily marketable — did not preempt the state-law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device, and thus plaintiffs would not have been injured. The Court — stressing that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (121 S. Ct. at 1020) — found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 1019.

B. The Extensive Regulatory History Of The Model 4004M Device.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 121 S. Ct. at 1015; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the Food and Drug Administration pursuant to the PMA process. The path to approval of the Model 4004M pacemaker lead at issue in this case demonstrates the thoroughness of that review. When the FDA approved Medtronic's application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of the predecessor, Model 4003 lead. Before the FDA

determined, in approving the Model 4004M PMA, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that the 4004M was safe and effective for its intended use, the device and its direct predecessor models (the Models 4004 and 4003) were rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004M.[1]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.
- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.
- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.
- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request, and required it to continue the investigation under the existing limits.
- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.

---

[1] This description is based on the affidavit of Charles H. Swanson, J.A. 98-119; see also Pet. App. 3a-4a.

- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983 required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing, and (2) "the fate of the implanted lead, in terms of potential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.

- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who had particular experience recognizing potential complications from the leads.

- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.

- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.

- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.

- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.

- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's

July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.

- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition, Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.
- In April 1986 — 30 months after Medtronic first filed a PMA request — the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.
- On May 23, 1986 the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that

the device was safe and effective for its intended use, and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.

- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.

- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.

- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had only been done on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.

- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic

had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA for the Model 4004M lead on March 28, 1990, subject to the same conditions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004M lead lasted *eight years* — from March 1982 to March 1990 — and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M and its predecessor models.

C. Petitioners' Case In The Lower Courts.

Elizabeth Kemp allegedly was injured when her Model 4004M lead malfunctioned. See Pet. App. 45a. Petitioners — Kemp and her husband, who filed only a derivative loss-of-consortium claim — thereafter brought this action against Medtronic in federal district court in Ohio on January 24, 1997. See *ibid.*

Petitioners' initial complaint raised 11 common-law and statutory product liability or derivative claims, alleging that the Model 4004M lead was defectively designed and manu-

factured and had inadequate warnings, that Medtronic had engaged in fraud and negligent misrepresentation under Ohio law, and that Medtronic had failed to comply with numerous FDA regulations. See Pet. App. 45a-46a. After pursuing discovery, however, petitioners narrowed their focus and placed emphasis on their negligence *per se* and fraud-on-the-FDA theories, challenging the sufficiency of Medtronic's submission of information in its PMA Supplement application, the accuracy of Medtronic's characterization of its scientific research findings and of the product's design, and Medtronic's post-approval regulatory compliance. Petitioners also contended that Medtronic made unauthorized changes to the design of the device, thereby rendering leads (such as Kemp's) made in conformance with the asserted modifications misbranded or adulterated, in violation of FDA regulations. See Brief of Plaintiffs-Appellants Elizabeth Kemp and Clifford Kemp, at 9-33, No. 99-3720 (6th Cir.) ("Brief of Appellants").

1. The District Court Proceedings.

On January 12, 1999, the district court granted Medtronic's motion for summary judgment, finding that the MDA preemption clause, 21 U.S.C. § 360k(a), preempted all claims raised in petitioners' complaint except to the extent those claims asserted that the device had not been manufactured in conformance with FDA requirements imposed by approving the device's PMA. Relying on *Lohr*, 518 U.S. at 495, the court held that state-law claims based on a violation of the FDA-approved specifications for the 4004M lead would not be preempted. However, the court held that petitioners had not specifically pled any such claim. See Pet. App. 66a-67a. The court therefore allowed petitioners to file "an amended complaint which alleges that the 4004M lead at issue deviated from the specifications approved by the FDA in the PMA and PMA Supplement." *Id.* at 67a.

Petitioners' amended complaint, however, restated the previously dismissed claims, as well as claims based on deviations from the approved specifications. See Pet. App. 72a. After dismissing the merely duplicative claims, on April 30, 1999, the court granted summary judgment on the new claims, holding as a factual matter that petitioners had presented no evidence that the Model 4004M failed to comply in any way with the FDA requirements applicable to the device, as established by its PMA process. *Id.* at 77a-80a.

2. The Court Of Appeals Decision.

On appeal to the Sixth Circuit, petitioners presented only three claims — negligence *per se*, fraud on the FDA, and the failure to warn petitioners of dangers based on information discovered after the PMA process. See Pet. App. 22a-37a; Brief of Appellants at 9-11, 49-63. The negligence *per se* claim, as "plaintiffs elected to distill" it below (Pet. App. 23a), alleged that "Medtronic failed to manufacture the Model 4004M as required by the FDA and thus sold a misbranded and/or adulterated product." *Id.* at 22a-23a. The fraud-on-the-FDA claim alleged that Medtronic "knowingly lied to the FDA and intentionally withheld information from the FDA in the application and approval process." Brief of Appellants at 61. The failure-to-warn claim, which was based on information "that Medtronic learned of * * * *after* the FDA's approval of the 4004/M PMA Supplement application and before implantation (and eventual failure) in Mrs. Kemp" (*ibid.*, emphasis supplied), alleged that Medtronic should have "issued additional or different post-sale warnings or timely recalled the product." *Id.* at 62. Petitioners also argued generally that if the Model 4004M as manufactured was different from the requirements approved by the FDA preemption should not be available. See *id.* at 49-52.[2]

---

[2] Petitioners' brief below confirms that these three claims were in fact the only ones presented to the Sixth Circuit. For example, the

After carefully analyzing the opinions in *Lohr* (Pet. App. 11a-15a), the court of appeals determined that the FDA's express approval of the proposed design, labeling, and manufacturing of the Model 4004M — coupled with the statutory prohibition on modifying those requirements without FDA approval — established specific federal requirements applicable under the MDA to the device. See Pet. App. 21a. Recognizing that *Lohr* had held that "Congress intended the preemption of some state-law causes of action" (Pet. App. 20a), thereby triggering preemption under 21 U.S.C. § 360k(a)(1), the court then proceeded to address petitioners' claims one by one.[3]

---

two-page introduction to petitioners' "Statement of Facts" explained the factual basis for their claims. According to petitioners:

- (1) "Medtronic made numerous misrepresentations to the FDA in its 4004/M PMA Supplement application in violation of FDA regulations and 21 U.S.C. §360e(b)." (Brief of Appellants at 9);
- (2) "Adding insult to injury, after FDA approval based on the above omissions and misrepresentations, Medtronic manufactured, marketed and sold a 4004/M *different* in design and manufacture from the 4004/M submitted to the FDA for review." (*Id.* at 10, emphasis in original); and
- (3) "In addition, Medtronic violated the FDA's general conditions of approval and FDA regulations in failing to provide the FDA with ongoing test results and relevant data which demonstrated that the 4004/M would fail. Medtronic obtained information post-approval that would have led any reasonable manufacturer to issue additional and/or different warnings and/or recall the product. Medtronic did nothing." (*Id.* at 10-11).

[3] In addition to express preemption arguments, Medtronic also made implied preemption arguments to the court of appeals (see, *e.g.*, Pet. App. 24a, 31a), but except with respect to the fraud-on-

The court of appeals rejected petitioners' negligence *per se* claims on several grounds. First, the court held that those claims had not been proven, because there was no evidence that Medtronic had violated the FDA's requirements in any fashion. See, *e.g.*, Pet. App. 25a (calling them "at best a tenuous assertion and, at worst, an outright mischaracterization of the record"). Second, the court held that "a jury verdict in plaintiff's favor on plaintiffs' negligence *per se* claims would amount to a state requirement 'different from, or in addition to,' the federal requirements" (*id.* at 30a), and thus found those claims preempted by § 360k(a). Finally, in the court's *per curiam* order denying petitioners' request for rehearing, the court determined that no such claims existed under Ohio law. See *id.* at 84a.[4]

The court of appeals disposed of petitioners' fraud-on-the-FDA claim by holding that it was expressly preempted by the MDA. See Pet. App. 34a-37a. Judge Moore agreed with this result but argued in her concurrence that the claim was instead impliedly preempted (see *id.* at 41a) — a ruling that the court's order denying rehearing seems to have adopted. See *id.* at 85a. Three weeks later, of course, this Court determined in *Buckman* that fraud-on-the-FDA claims such as petitioners were impliedly preempted by the MDA. See 121 S. Ct. at 1017.

Finally, the court of appeals held that petitioners' failure-to-warn claim was expressly preempted (Pet. App. 37a-38a) to the extent it challenged warnings approved by the FDA

---

the-FDA claim the court focused exclusively on express preemption.

[4] In their petition for rehearing petitioners also attempted to expand the scope of their negligence *per se* claim. However, the court of appeals found that, "[t]o the extent that [petitioners] would have the Court view" their fraud-against-the-FDA claims also to be negligence *per se* claims, those claims did not state a cause of action for negligence *per se* under Ohio law. See Pet. App. 84a.

and that the claim was waived to the extent it was based on warnings that should have been developed as a result of analyzing data obtained *after* the FDA's approval. *Id.* at 38a. The court noted that "[i]t [was] difficult to determine * * * the underlying basis of plaintiffs' claim as presented to the district court below." *Id.* at 37a. In their petition for rehearing, petitioners clarified that on appeal they were raising specifically "a post-FDA approval failure to warn claim with a supporting factual basis" (Plaintiffs/Appellants' Petition for Rehearing With Suggestion For Rehearing *En Banc*, at 8), but the court held that this claim "should have been clarified below in a timely manner" (Pet. App. 86a) and therefore had been waived. See *id.* at 85a-86a.

REASONS FOR DENYING THE PETITION

Petitioners assert that review is necessary here because of the disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. But even if there were confusion about the preemptive scope of the MDA, this case would be a most inappropriate vehicle in which to resolve that confusion, because petitioners have presented no claims to this Court that were held preempted below (see Part I.A). Moreover, in light of this Court's recent decision in *Buckman*, the Court should allow the lower courts time to revisit preemption issues under the MDA (see Part I.B). Finally, as we explain in Part I.C, the lower courts are in significantly less disarray than petitioners suggest. In any event, given the extensive FDA scrutiny of the Model 4004M pacemaker lead, the Sixth Circuit's decision is plainly correct (see Part II).

I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR.*

A. Petitioners Have Preserved No Claims That Would Be Affected By This Court's Intervention.

"While this Court decides questions of public importance, it decides them in the context of meaningful litigation. Its function in resolving conflicts among the Courts of Appeals is judicial, not simply administrative or managerial." *The Monrosa* v. *Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). Even if this Court were to adopt petitioners' interpretation of the MDA preemption provision, the judgment of the court of appeals would stand. Thus, were this Court to grant review, it would be in the position to deliver nothing but an improper advisory opinion.

Utterly missing from the petition is any real description of what claims the petitioners made below and how those claims were addressed. In fact, petitioners raised only three claims in the Sixth Circuit — fraud on the FDA, negligence *per se*, and failure to warn based on data learned after FDA approval, see page 11, *supra — none of which is before this Court.* Petitioners acknowledge that their fraud-on-the-FDA claim is preempted in light of *Buckman* and do not raise it in the petition. See Pet. 13 n.4. And they acknowledge that they cannot present their negligence *per se* claim to this Court, because that claim was partially "resolved on state-law grounds." *Ibid.*; see also *id.* at 8 n.2; Pet. App. 84a. Finally, petitioners' failure-to-warn claim was presented to the Sixth Circuit on the ground that Medtronic's failure to warn of evidence acquired after FDA approval violated state law (see Brief of Appellants at 33, 61-63) — but the court of appeals held that petitioners had waived such a claim. See Pet. App. 85a-86a. In sum, there is no claim preempted by the MDA that was both raised below and presented in the petition.

Even if petitioners had preserved product liability claims beyond their negligence *per se* claim, those claims would not present preemption issues to this Court. Petitioners' theory of product liability, which was developed through 20 months of discovery, see Brief of Appellants at 6, revolved around Medtronic's asserted failure to abide by FDA requirements. See *id.* at 10; *id.* at 32 ("Even if there is some type of specific federal requirement applicable to the 4004/M, Medtronic is still not entitled to preemption immunity. Medtronic marketed and sold a 4004/M different in manufacture and design than the 4004/M submitted for FDA review."); *id.* at 50-51. *The lower courts explicitly found, however, that Medtronic did not violate those requirements*. See Pet. App. 23a-27a; see, *e.g.*, *id.* at 25a ("[P]laintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record."). Thus, any remaining product liability claim that petitioners might attempt to assert, even if not preempted, was found to be factually unsupported.

The petition engages in an extensive academic discussion on the state of the law of MDA preemption, but it never explains how any of petitioners' claims that have evidentiary support in the record and that were not waived below would be affected by a favorable decision. (And it would, we believe, be most unfair for petitioners to attempt to provide that explanation for the first time in a reply brief, to which we would have no opportunity to respond.) Because the Court "'reviews judgments, not statements in opinions,'" *Johnson* v. *De Grandy*, 512 U.S. 997, 1003 n.5 (1994) (quoting *California* v. *Rooney*, 483 U.S. 307, 311 (1987) (*per curiam*) (quoting *Black* v. *Cutter Labs.*, 351 U.S. 292, 297 (1956))), there is no reason to grant certiorari.

B. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption of State-Law Tort Actions Before Revisiting The Issue Itself.

While the *Buckman* Court, which focused on implied preemption, "express[ed] no view on whether [fraud-on-the-FDA] claims are subject to express pre-emption under 21 U.S.C. § 360k," 121 S. Ct. at 1017 n.2, this Court should nonetheless allow the lower courts time to consider the implications of *Buckman* before expending further effort on issues that the lower courts may resolve themselves in light of that case.

At least three aspects of the *Buckman* decision may assist courts in determining the preemptive scope of the PMA process. First, the Court in *Buckman*, as in *Lohr*, stressed how thorough the PMA process is as compared to the 510(k) process found non-preemptive in *Lohr*. See 121 S. Ct. at 1015. Second, the Court clarified that while *Lohr* "can be read to allow *certain* state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 1020 (emphasis added). Finally, the Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought to achieve under the MDA scheme and stressed how allowing state law claims of fraud-on-the-FDA would disrupt that balance. *Id.* at 1017.

All three aspects of *Buckman* may well influence lower courts' views about the preemptive effect of the PMA process. For example, the first reinforces the accuracy of the Sixth Circuit's holding that *Lohr*'s analysis of the preemptive scope of the 510(k) process is not applicable to the PMA process. Those few courts that have found otherwise may choose to reconsider those holdings in light of *Buckman*. See, *e.g.*, *Martin* v. *Medtronic, Inc.*, __ F.3d __, 2001 WL 682097, at *10 (5th Cir. 2001) (citing *Buckman* in contrast-

ing the 510(k) approval process with PMA review). Second, this Court acknowledged that at least some state-law claims must be preempted by the MDA; to the extent lower courts had found otherwise those courts may now conclude that they were incorrect. Finally, it is hard to see how the "delicate balance" cut by the MDA would not be disrupted by allowing states to impose conflicting requirements on devices approved by the FDA pursuant to the arduous PMA process. As the dissenting judge stressed in *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), allowing state-law failure-to-warn claims might impose "conflicting labeling requirements in various states" (*id.* at 968) that differed from the FDA's "unambiguous conclusion about how * * * competing considerations should be resolved" (*id.* at 967, quoting *Lohr*, 518 U.S. at 501).

The Eighth Circuit granted rehearing en banc in *Brooks*, where the majority had found failure-to-warn claims not to be preempted, *the day after this Court decided Buckman*. See 246 F.3d 1149. Just as that court now is reconsidering whether state-law claims against manufacturers of devices approved through the PMA process are preempted, so too other courts may decide to revisit the issue. Thus, rather than granting review in a procedurally problematic case on an issue that may never require this Court's attention, this Court should deny the petition.

C. While There Is Some Inconsistency In The Lower Courts, It Is More Limited Than Petitioners Assert.

Petitioners make a great deal about the "deep post-*Lohr* split in authority," asserting that there is a conflict "in two important and related respects." Pet. 14. Their first issue, however — "whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims" (*ibid.*) — is in fact nothing but a confused summary of one

aspect of their second issue. That second issue in turn has two parts; petitioners assert that there are conflicts both on whether the PMA process imposes specific, federal requirements and whether any duties imposed through state-law damages actions can be preempted after *Lohr*. While some courts have misinterpreted *Lohr* on both what federal requirements may be preemptive and on whether state common-law claims may be preempted, the great weight of authority favors the Sixth Circuit's position on both issues.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to the device are preemptive under the MDA. See 518 U.S. at 500-501; Pet. App. 14a-15a.[5] Based on this Court's discussion of the "rigorous" nature of the PMA process, and this Court's comparison between 510(k)-process requirements (which the Court found to be "important but entirely generic concerns") and the PMA process (which fits in this Court's discussion of "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements") (see *Lohr*,

---

[5] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 24-25, *infra*.

518 U.S. at 501), the vast majority of courts have found PMA approval and the resultant bar on changes to a FDA-approved device to create specific federal requirements that preempt conflicting state common-law damages actions. See, *e.g.*, Pet. App. 20a; *Martin*, 2001 WL 682097, at *10; *Brooks*, 236 F.3d at 963-964, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

Petitioners identify (at Pet. 16) only two federal courts of appeals or state courts of last resort (*cf.* S. Ct. R. 10) that did not find PMA approval to be preemptive — *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while inconsistent with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found parts of the requirements imposed through the PMA process not to be "specific" (167 F.3d at 1376), while acknowledging that other aspects *were* specific (*ibid.*). The FDA's "conditions of approval," barring modification of a device without FDA consent, were specific federal requirements, the court acknowledged, but it found that these were not "'applicable under [the MDA] to the device.'" *Ibid.* (quoting 21 U.S.C. § 360k(a)(1)). This latter holding is not only inconsistent with the former holding but also contrary to *Lohr*, which focused on whether federal requirements were specific or general requirements, not whether they were applicable exclusively to the specific device. See 518 U.S. at 500 ("federal requirements must be 'applicable to the device in question" under FDA regulations). In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final

Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that all aspects of the PMA process were not specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: first, the court held that "premarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*) — a statement that, while perhaps true for the device at issue in *Weiland*, certainly was not true in this case, where the FDA repeatedly required modifications of the product or its labeling (see pages 5-9, *supra*); second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, this decision is plainly incorrect.[6]

---

[6] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 16-17 n.5), to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), while the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination in the PMA process that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common-law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in ques-*

2. On the state side of the *Lohr* preemption equation, petitioners assert that there is a "profound" split of authority over whether state-law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[7] a decision that is plainly correct under *Lohr* (see pages 25-26, *infra*). Only one federal court of appeals or state court of last resort (*cf.* S. Ct. R. 10) has relied on a contrary finding to limit the preemptive scope of the MDA — the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997). That case is one of the earliest appellate decisions to interpret *Lohr* and plainly misinterprets it in a variety of ways.[8]

For example, the Tenth Circuit never directly considered whether a finding of liability under a state-law duty would "have the effect of establishing a substantive requirement of a specific device" — even though the court earlier had acknowledged that such inquiry was necessary. 111 F.3d at

---

tion, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

[7] See, *e.g.*, Pet. App. 34a-35a, 37a; *Martin*, 2001 WL 682097, at *6; *Brooks*, 236 F.3d at 963, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[8] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, through the 510(k) process, it held that the FDA's 510(k) review led to specific federal requirements — despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common-law damages actions impose "requirements" that can be preempted by federal requirements. See pages 25-26, *infra*.[9] This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. There is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*, in light of the overwhelming weight of authority of other courts of appeals and the opinion of the FDA (see page 27 n.11, *infra*) that such state-law claims may be preempted.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE-LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur there must be a federal requirement, a state requirement, and some "differen[ce]" be-

---

[9] Petitioners' assertion that the Supreme Court of Kentucky, in *Niehoff*, 950 S.W.2d 816, held that state-law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common-law damages claims. See *id.* at 822. As discussed above (at n.6), the court also focused on the significant differences between the PMA process and the IDE process.

tween the two. See 518 U.S. at 500. Both criteria are satisfied here.

1. The Sixth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific).

The decision below makes eminent sense. The PMA process imposes a host of specific federal "requirement[s]" on devices such as the Model 4004M lead.[10] We described above (at pages 5-9) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plan to distribute the 4004M. That process entailed extended federal review and approval of "the product's design, testing, in-

---

[10] Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360(e). See 21 U.S.C. §§ 331(e), 360e(f)), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

tended use, manufacturing methods, performance standards and labeling" and is "specific to the product." Pet. App. 18a, quoting *Mitchell*, 126 F.3d at 913. And most important, approval under the PMA entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477, citing 21 U.S.C. § 360e(d)(2). The determination that a product is safe and effective, weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (21 U.S.C. § 360c(a)(2)(C)), after a process characterized by the Supreme Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 121 S. Ct. at 1018), is of necessity the determination that the details of that device are an appropriate compromise that should not be modified by state law.

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue *by expressly exempting it* (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary were the PMA process not a requirement otherwise preemptive of the state law.

2. The Sixth Circuit also correctly found that petitioners' state-law claims, to the extent those claims were based on a showing that the device differed from the one required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes preempt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar

requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part). The court below, like *Lohr*, found that state-law claims that impose a duty identical to federal requirements would not be preempted. See Pet. App. 33a. But where a state-law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Here, the lower courts held that the PMA imposed a specific requirement on Medtronic to use platinum sputtering, but did not mandate that the sputtering be of a uniform 500 Å thickness. Were a jury to impose liability on Medtronic under Ohio law for not having kept its platinum sputtering at that uniform thickness, it would plainly be imposing a different, additional requirement on the 4004M pacemaker lead — and an additional requirement that could itself differ from requirements imposed in other states.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run

roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.[11]

* * * * *

In the final analysis, petitioners present this Court little evidence of a significant split in authority below, even less explanation for why the issue presented deserves the Court's attention at the present time, and no discussion whatsoever about the fact that no state-law claims preserved in their petition *were* preempted by FDA requirements imposed by the device's PMA. Thus, this Court is being asked merely to comment on a theoretical dispute about the scope of preemption under the MDA, rather than to resolve a specific issue in the context of active litigation.

---

[11] In Part C of their brief, petitioners purport to present evidence of the United States' view on the questions presented herein. But the Solicitor General's view about whether *fraud-on-the-FDA* claims are expressly preempted, see Pet. 23-24, has no bearing on this case, where that claim — which raises significantly different concerns than product liability theories — has been dropped in light of *Buckman*. Similarly, the positions taken in the Solicitor General's brief in *Smith Industries Med. Systems, Inc.* v. *Kernats*, No. 96-1405, 118 S. Ct. 684 (1998) (Mem.), were based on the FDA's then-pending proposed rulemaking procedure. See United States Brief in *Kernats*, at 14, 19-20. The FDA has since withdrawn that proposed rule, see Pet. 23 n.8, and thus there is no evidence that those positions reflect the current views of the agency. In any event, petitioners' reliance on the views of the United States is selective. The Solicitor General has only recently taken the position that "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts * * * ." United States Brief in *Buckman*, at 12 n.1.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

THOMAS M. PARKER
Roetzel & Andress
222 South Main Street
Akron, Ohio 44308
(330) 376-2700

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

JULY 2001